CLEAN VERSION OF CLAIMS AS AMENDED

1. A method for making an insulin-containing particulate product, comprising:

contacting an insulin-containing feed solution with a compressed anti-solvent fluid to precipitate insulin-containing particles, the feed solution including the insulin in a cosolvent system including at least a first organic solvent and a second organic solvent that are mutually soluble; and

separating the insulin-containing particles from the anti-solvent fluid.

2. The method of claim 1, wherein insulin is at least about an order of magnitude more soluble in the first organic solvent than in the second organic solvent.

3. The method of claim 1, wherein the first organic solvent and the second organic solvent are present in the solution at a volume ratio of the second organic solvent to the first organic solvent of larger than about 30:70.

4. The method of claim 1, wherein the first organic solvent and the second organic solvent are present in the cosolvent system at a volume ratio of the second organic solvent to the first organic solvent of from about 50:50 to about 90:10.

5. The method of claim 1, wherein the concentration of insulin in the cosolvent system is smaller than about 3 mg of insulin per milliliter of the feed solution.

6. The method of claim 1, wherein the concentration of insulin in the cosolvent system is in a range of from about 0.3 to about 3 mg of insulin per mL of the solution.

7. The method of claim 1, wherein the first organic solvent is selected from the group consisting of DMSO and DMFA.

8. The method of claim 7, wherein the second organic solvent is an alcohol.

9. The method of claim 7, wherein the second organic solvent is a C1-C5 alkanol.

10. The method of claim 1, wherein the compressed anti-solvent , during the contacting, is at a reduced pressure of larger than about 0.8 and a reduced temperature of larger than about 0.95.

11. The method of claim 10, wherein the compressed anti-solvent, during the contacting, is at a reduced pressure of larger than about 0.9.

12. The method of claim 10, wherein the compressed anti-solvent, during the contacting, is in a supercritical state.

13. The method of claim 10, wherein the compressed anti-solvent comprises compressed carbon dioxide.

14. The method of claim 1, wherein the feed solution is substantially free of amphiphilic materials that improve solubility of the insulin in the feed solution through hydrophobic ion pairing with the insulin.

15. The method of claim 1, wherein, during the contacting step, the solution is introduced into the compressed anti-solvent fluid through an opening having a cross-sectional area available for flow that is larger than about 1 square millimeter.

16. The method of claim 15, wherein the solution, when introduced into the compressed anti-solvent fluid has a direction of flow that is at an angle of from about 45° to about 180° relative to the direction of flow of the compressed anti-solvent fluid.

17. The method of claim 1, wherein the cosolvent system includes water, if at all, in an amount of smaller than about 5 weight percent.

18. The method of Claim 1, wherein the cosolvent system is substantially free of water.

19. The method of claim 1, where at least a portion of the insulin in the feed solution is in the form of colloidal particles dispersed in the cosolvent system.

20. (Amended). The method of claim 1, wherein the feed solution includes a biocompatible polymer and the insulin-containing particles comprise multi-component particles including insulin and the biocompatible polymer.

21. The method of claim 20, wherein the insulin is more soluble in the first organic solvent than is the biocompatible polymer, and the biocompatible polymer is more soluble in the second organic solvent than the insulin.

22. The method of claim 20, wherein the biocompatible polymer is hydrophobic, the first organic solvent being a polar solvent for the insulin and the second organic solvent being a nonpolar solvent for the biocompatible polymer.

23. The method of claim 20, wherein the first organic solvent is substantially miscible with water and the second organic solvent is substantially immiscible with water.

24. The method of claim 20, wherein the second organic solvent comprises at least one of methylene chloride, formaldehyde, dioxolane, chloroform, benzene, ethyl ether, toluene, xylene, 1,3-dioxane and THF.

25. The method of claim 24, wherein the first organic solvent comprises an alcohol.

26. The method of claim 25, wherein the first organic solvent comprises a C_1-C_5 alkanol.

27. The method of claim 26, wherein the first organic solvent comprises at least one of methanol, ethanol and isopropanol.

28. The method of claim 26, wherein the second organic solvent comprises methylene chloride.

29. The method of claim 26, wherein the feed solution further comprises an acid dissolved in the cosolvent system.

30. (Amended) The method of claim 29, wherein the acid comprises an inorganic acid.

31. The method of claim 29, wherein the acid comprises hydrochloric acid.

32. The method of claim 20, wherein the method comprises, prior to the contacting step, preparing the feed solution, comprising mixing a first solution having the insulin dissolved therein with a second solution having the biocompatible polymer dissolved therein, the first solution including the first organic solvent and the second solution including the second organic solvent.

33. The method of claim 32, wherein during the mixing step, the second solution is added to the first solution.

34. The method of claim 32, wherein the first solution comprises an acid to increase the solubility of the insulin in the first solution.

35. The method of claim 34, wherein the second solution is prepared by first dissolving the acid with the second organic solvent and then dissolving the insulin in the second organic solvent.

36. The method of claim 30, wherein the weight ratio of the insulin to the polymer in the feed solution is larger than about 5:95.

37. The method of claim 20, wherein the weight ratio of the insulin to the polymer in the feed solution is in a range of from about 5:95 to about 50:50.

38. The method of claim 20, wherein both of the first organic solvent and the second organic solvent are substantially soluble in the compressed anti-solvent fluid.

39. The method of claim 20, wherein the compressed anti-solvent fluid, during the

contacting step, is at a reduced pressure of larger than about 0.5 relative to the critical pressure of the anti-solvent fluid.

40. The method of claim 39, wherein the compressed anti-solvent fluid, during the contacting step, is at a reduced temperature of larger than about 0.95 relative to the critical temperature of the anti-solvent fluid.

41. The method of claim 40, wherein the compressed anti-solvent fluid, during the contacting step, is at a reduced pressure of larger than about 0.8 relative to the critical pressure of the anti-solvent fluid.

42. The method of claim 20, wherein the compressed anti-solvent fluid, during the contacting step, is in a supercritical state.

43. The method of claim 20, wherein the compressed anti-solvent fluid comprises compressed carbon dioxide.

44. The method of claim 20, wherein the compressed anti-solvent fluid consists essentially of only compressed carbon dioxide.

45. The method of claim 20, wherein during the contacting step, the feed solution is introduced into a flowing stream of the compressed anti-solvent fluid, the direction of flow of the feed solution, when introduced into the flowing stream of the compressed anti-solvent fluid, is at an angle of from about 45° to about 180° relative to the direction of flow of the compressed anti-solvent fluid.

46. The method of claim 20, wherein the contacting step is conducted under conditions so that the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 50 percent.

47. The method of claim 20, wherein the contacting step is conducted under conditions so that the multi-component particles have a degree of encapsulation of the insulin by the polymer of greater than about 70 percent.

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48. (Amended) The method of claim 20, wherein the biocompatible polymer includes a poly(lactic acid).